TRACON Pharmaceuticals Announces Positive Data from Ongoing Phase 1b/2 Trial of TRC105 in Hepatocellular Carcinoma

January 22, 2019

Three Confirmed Partial Responses (20%) by RECIST and > 50% Reductions of Alpha Fetoprotein in Half of Patients Treated to Date with Combination of TRC105 and Nexavar®

Data Presented at ASCO 2019 Gastrointestinal Cancers Symposium

SAN DIEGO, Jan. 22, 2019 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration and fibrotic diseases, today announced that positive clinical data from its ongoing Phase 1b/2 study of TRC105 and Nexavar® (sorafenib) in patients with advanced hepatocellular carcinoma (HCC) were presented in a poster presentation at the ASCO 2019 Gastrointestinal Cancers Symposium in San Francisco on January 18, 2019.

Data from the ongoing open-label, non-randomized study were presented by Dr. Kanwal Raghav from the University of Texas MD Anderson Cancer Center. Key results included:

- Confirmed partial response by RECIST 1.1 occurred in 3 of 15 (20%) evaluable patients and a reduction of 50% or greater in alpha fetoprotein (AFP) concentration occurred in 8 of 16 (50%) evaluable patients. Reduction in AFP, a tumor marker expressed in patients with HCC, in early treatment may help predict a favorable response to treatment.
- Adverse events expected of each drug did not increase in frequency or severity when TRC105 and sorafenib were administered concurrently.
- TRC105 trough concentrations were lower in HCC patients compared with prior TRC105 studies in other tumor types, and weekly dosing at the recommended Phase 2 dose of TRC105 of 10 mg/kg, rather than every other week dosing, was required to exceed target concentrations consistently. This may reflect increased target mediated clearance in HCC patients via fibrotic/cirrhotic liver disease.
- Anti-drug antibody (ADA) was observed more frequently in patients with HCC (76%) compared with prior studies of TRC105 in other tumor types (e.g., in RCC, sarcoma, and lung cancer patients where ADA has been ~5%) and may have influenced pharmacokinetics in individual patients.

“We continue to be encouraged by the safety and activity of TRC105 in combination with Nexavar in patients with liver cancer,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “Importantly, the response rate from the current trial is superior to historic response rates reported from multiple trials of Nexavar as a single agent. We expect to complete enrollment of the current multicenter study by the end of this year, at which time we expect to correlate response with the soluble baseline biomarkers that are being collected as part of the study.”

The poster is available on TRACON’s website at: www.traconpharma.com/publications.php

About Carotuximab (TRC105)

TRC105 is a novel, clinical stage antibody to endoglin, a protein overexpressed on proliferating endothelial cells that is essential for angiogenesis, the process of new blood vessel formation. TRC105 is currently being studied in a pivotal Phase 3 trial in angiosarcoma and multiple Phase 2 clinical trials, in combination with VEGF inhibitors, as well as in a Phase 1 trial with Opdivo. TRC105 has received orphan designation for the treatment of soft tissue sarcoma in both the U.S. and EU. The ophthalmic formulation of TRC105, DE-122, is currently in a randomized Phase 2 trial for patients with wet AMD. For more information about the clinical trials, please visit TRACON’s website at www.traconpharma.com/clinical_trials.php.

About TRACON

TRACON develops targeted therapies for cancer and ophthalmic diseases. The Company’s clinical-stage pipeline includes: TRC105, an endoglin antibody that is being developed for the treatment of multiple cancers; DE-122, the ophthalmic formulation of TRC105 that is being developed in wet AMD through a collaboration with Santen Pharmaceutical Company Ltd.; TRC102, a small molecule being developed for the treatment of lung cancer and glioblastoma; and TRC253, a small molecule being developed for the treatment of prostate cancer. TRACON is actively seeking additional corporate partnerships whereby it leads regulatory and clinical development and shares in the cost and risk of clinical development and commercialization of new product candidates. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the United States. To learn more about TRACON and its product candidates, visit TRACON's website at www.traconpharma.com.

Forward-Looking Statements

Statements made in this press release regarding matters that are not historical facts are “forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding TRACON's plans to further develop its product candidates, expectations regarding the timing and scope of clinical trials and availability of clinical data, expected development milestones, and potential utility of TRACON’s product candidates. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether TRACON or others will be able to complete or initiate clinical trials on TRACON’s expected timelines, if at all; the fact that future preclinical studies and clinical trials may not be successful or otherwise consistent with results from prior studies; the fact that TRACON has limited control over whether or when third party collaborators complete on-going trials or initiate additional trials of TRACON’s product candidates; potential changes in regulatory requirements in the United States and foreign countries; TRACON’s reliance on third parties for the development of its product candidates, including the conduct of its clinical trials and manufacture of its product candidates; whether TRACON will be able to obtain additional financing; and other risks described in TRACON’s filings with the Securities and Exchange Commission under the heading “Risk Factors”. All forward -looking statements contained in this press release speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. TRACON undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Company Contact:	Investor Contact:
Mark Wiggins	Andrew McDonald
Chief Business Officer	LifeSci Advisors LLC
(858) 550-0780 ext. 236	646-597-6987
mwiggins@traconpharma.com	Andrew@lifesciadvisors.com

Tracon Pharmaceuticals, Inc. Logo

Source: TRACON Pharmaceuticals, Inc.